IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Before the Board of Patent Appeals and Interferences

Applicant : Loretta A. Fitzgerald
Serial No. : 10/680,347
Filed : October 7, 2003
For : A System for Processing Patient Radiation Treatment Data
Examiner : John Fernando Ramirez
Art Unit : 3737

APPEAL BRIEF

May It Please The Honorable Board:

Appellants initiate a new appeal under 37 CFR 41.27 in response to the Rejection, dated September 26, 2007, of claims 1-18 of the above-identified application. The fee of five hundred dollars ten ($510.00) for filing this Brief is to be charged to Deposit Account No. 19-2179. Enclosed is a single copy of this Brief.

Please charge any additional fee or credit any overpayment to the above-identified Deposit Account.

Appellants do not request an oral hearing.

I. REAL PARTY IN INTEREST

The real party in interest of Application Serial No. 10/680,347 is the Assignee of record:
Siemens Medical Solutions Health Services Corporation
51 Valley Stream Parkway
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which merged into Siemens Medical Solutions USA Inc. on 1 January 2007.

II. RELATED APPEALS AND INTERFERENCES

There are currently, and have been, no related Appeals or Interferences regarding Application Serial No. 10/680,347.

III. STATUS OF THE CLAIMS

Claims 1-18 are rejected and the rejection of claims 1-18 are appealed.

IV. STATUS OF AMENDMENTS

All amendments were entered and are reflected in the claims included in Appendix I. No additional amendments were made to the claims which were not previously entered.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 provides a system for processing data concerning patient radiation treatment (paragraph [0003]). An input processor (paragraph [0003]) receives data identifying a first radiation dose, received by a particular anatomical part of a patient, from a radiation source external to a patient and a second radiation dose, received by the particular anatomical part of the patient from a radiation source internal to the patient and implanted within the patient (paragraph [0003]; [0023]; [0004]; Fig. 2, reference nos. 107 and 115). A data processor combines data representing the first and second dose by automatically summing values representing the first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by the particular anatomical part of the patient (paragraph [0018]). A storage processor automatically stores the combined therapeutic dose value in an electronic record associated with the patient in a repository (paragraphs [0018]-[0023]; Fig. 1, reference nos. 2, 4 and 5; Fig. 2, reference no. 127) concurrently accessible by a plurality of different healthcare workers using remote devices (paragraph [0017]; Fig. 1, reference no. 3). A workflow processor schedules and manages a sequence of tasks involved in producing a treatment plan using the electronic record including the combined therapeutic dose value (paragraph [0017]; paragraph [0022]; Fig. 1, reference no. 4; Fig. 2).

Dependent claim 2 includes all the features of independent claim 1, along with the additional feature that the input processor automatically acquires patient radiation survey record data from radiation survey equipment indicating radiation levels emitted by a patient (paragraph [0019]; paragraph [0021]; Fig. 5). The storage processor stores the acquired patient radiation survey record data in the repository (paragraphs [0017]; Fig. 1, reference no. 2).

Dependent claim 3 includes all the features of independent claim 1, along with the additional feature that the data processor automatically populates a patient radiation survey record from the data derived from radiation survey equipment indicating radiation levels emitted by a patient (paragraph [0019]; paragraph [0021]; Fig. 5). The radiation source internal to the patient includes at least one of, (a) an implanted device, (b) an intra-vascular radiation treatment source, (d) a temporarily inserted radiation source, (e) a permanently inserted radiation source, (f) a diagnostic related radiation source and (g) a therapeutic radiation source.

Dependent claim 4 includes all the features of independent claim 1, along with the additional feature of a rules processor for initiating generation of an alert message for communication to a healthcare worker, in response to the combined therapeutic dose value and automatically initiating generation of an alert message for communication to a healthcare worker, in response to determining inappropriate radiation settings of a radiation imaging or therapy device in response to the combined therapeutic dose value (paragraph [0017]).

Dependent claim 8 includes all the features of independent claim 1, along with the additional feature of a communication interface for initiating communication of an alert message to a user identifying the combined therapeutic dose value associated with the patient (paragraph [0017]).

Dependent claim 11 includes all the features of independent claim 1, along with the additional feature of an interface processor for using the combined therapeutic dose value in configuring a radiation therapy device for delivering a radiation treatment to a patient (paragraph [0016]; Fig. 1, reference no. 6).

Independent claim 12 provides a system for processing data concerning patient radiation treatment (paragraph [0003]). An input processor (paragraph [0003]) receives data identifying a first radiation dose received by a particular anatomical part of a patient, from a radiation source external to a patient. A second radiation dose is received by the particular anatomical part of the patient from the radiation source internal to the patient and implanted within the patient (paragraph [0003]; [0023]; [0004]; Fig. 2, reference nos. 107 and 115). A data processor combines data representing the first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by the particular anatomical part of the patient (paragraph [0018]). A rules processor is included for automatically initiating generation of an alert message (paragraph [0017]) for communication to a healthcare worker, in response to determining inappropriate radiation settings of a radiation imaging or therapy device in response to the combined therapeutic dose value. A storage processor automatically stores the combined therapeutic dose value in an electronic record associated with the patient in a repository (paragraphs [0018]-[0023]; Fig. 1, reference nos. 4 and 5; Fig. 2, reference no. 127) concurrently accessible by a plurality of healthcare workers using remote devices (paragraph [0017]; Fig. 1, reference no. 3). A task manager updates a record indicating a task to be performed by including an additional task in response to the combined therapeutic dose value (paragraphs [0017]-[0018] paragraph [0022]; Fig. 1, reference no. 4; Fig. 2).

Dependent claim 13 includes all the features of independent claim 12, along with the additional feature that the input processor receives data identifying a radiation value emitted by a radiation source implanted within a patient (paragraph [0026]). The task manager updates a record to indicate a perimeter is to be designated identifying an area around the patient to be avoided by other personnel, in response to the combined therapeutic dose value (paragraph [0019]; Fig. 7).

Independent claim 14 provides a method for processing data concerning patient radiation treatment (paragraph [0003]). Data identifying a first radiation dose, received by a particular anatomical part of a patient, from a radiation source external to a patient is received. A second radiation source, received by the particular anatomical part of the patient from a radiation source internal to the patient and implanted within the patient, is provided (paragraph [0003]; [0023]; [0004]; Fig. 2, reference nos. 107 and 115). Data representing the first and second dose is combined by automatically summing values representing the first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by the particular anatomical part of the patient (paragraph [0018]). The combined therapeutic dose value is automatically stored in an electronic record associated with the patient in a repository (paragraphs [0018]-[0023]; Fig. 1, reference nos. 4 and 5; Fig. 2, reference no. 127) concurrently accessible by a plurality of healthcare workers using remote devices (paragraph [0017]; Fig. 1, reference no. 3). A sequence of tasks involved in producing a treatment plan are scheduled and managed using the electronic record including the combined therapeutic dose value (paragraph [0017] paragraph [0022]; Fig. 1, reference no. 4; Fig. 2).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 3, 7, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wessol et al., (U.S. Patent No. 6,965,847), hereinafter "Wessol," in view of Burdette et al. (U.S. Patent No. 6,129,670), hereinafter "Burdette," in view of Kestin et al. *"Pathologic Evidence of Dose-Response and Dose-Volume Relationships for Prostate Cancer Treated with Combined External Beam Radiotherapy and High-Dose-Rate Brachytherarpy,"* hereinafter "Kestin," in view of Helmick et al. *"Evaluation of Post-Plan Dosimetery Using TRUS and CT After Transperineal Prostate Seed Implant"* hereinafter "Helmick."

Claims 2, 4-6, 8 10 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wessol et al., (U.S. Patent No. 6,965,847), hereinafter "Wessol," in view of Burdette et al. (U.S. Patent No. 6,129,670), hereinafter "Burdette," in view of Kestin et al. *"Pathologic Evidence of Dose-Response and Dose-Volume Relationships for Prostate Cancer Treated with Combined External Beam Radiotherapy and High-Dose-Rate Brachytherarpy,"* hereinafter "Kestin," in view of Helmick et al. *"Evaluation of Post-Plan Dosimetery Using TRUS and CT After Transperineal Prostate Seed Implant"* hereinafter "Helmick," in view of Good (U.S. Patent No. 6,099,457) and in further view of Widener et al. (U.S. Patent Pub. No. 2004/0236207), hereinafter "Widener."

Claims 15-18 have been newly added by a previous response. Claims 15-18 are not specifically rejected or accepted by the Rejection. However, Applicant respectfully submits that claims 15-18 are allowable over Wessol, Burdette, Kestin, Helmick, Good and Widener, when taken alone or in any combination.

VII. ARGUMENT

Applicant respectfully submits that Wessol, Burdette, Kestin and Helmick, when taken alone or in any combination, do not make the present claimed invention unpatentable. Additionally, Wessol, Burdette, Kestin, Helmick, Good and Widener, when taken alone or in any combination, do not make the present claimed invention unpatentable. Thus, reversal of the Final Rejection (hereinafter termed "rejection") of claims 1-18 under 35 U.S.C. § 103(a) is respectfully requested.

Rejection of claims 1, 3, 7, 9 and 11 under 35 U.S.C. 103(a) over Wessol (U.S. Patent No. 6,965,847), in view of Burdette (U.S. Patent No. 6,129,670), in view of Kestin *"Pathologic Evidence of Dose-Response and Dose-Volume Relationships for Prostate Cancer*

Treated with Combined External Beam Radiotherapy and High-Dose-Rate Brachytherarpy,"* in view of Helmick *"Evaluation of Post-Plan Dosimetery Using TRUS and CT After Transperineal Prostate Seed Implant"

Reversal of the rejection of claims 1, 3, 7, 9 and 11 under 35 U.S.C. 103(a) as being unpatentable over Wessol (U.S. Patent No. 6,965,847), in view of Burdette (U.S. Patent No. 6,129,670), in view of Kestin *"Pathologic Evidence of Dose-Response and Dose-Volume Relationships for Prostate Cancer Treated with Combined External Beam Radiotherapy and High-Dose-Rate Brachytherarpy,"* in view of Helmick *"Evaluation of Post-Plan Dosimetery Using TRUS and CT After Transperineal Prostate Seed Implant"* is respectfully requested because the rejection makes crucial errors in interpreting the cited reference. The rejection erroneously states that claims 1, 3, 7, 9 and 11 are made unpatentable by Wessol, Burdette, Kestin and Helmick.

Overview of the Cited References

Wessol describes a computer readable media for ultimately developing a dosimetry plan for a treatment volume irradiated during radiation therapy with a radiation source concentrated internally within a patient or incident from an external beam. The dosimetry plan is available in near "real-time" because of the novel geometric model construction of the treatment volume which in turn allows for rapid calculations to be performed for simulated movements of particles along particle tracks therethrough. The particles are exemplary representations of alpha, beta or gamma emissions emanating from an internal radiation source during various radiotherapies, such as brachytherapy or targeted radionuclide therapy, or they are exemplary representations of high-energy photons, electrons, protons or other ionizing particles incident on the treatment volume from an external source. In a preferred embodiment, a medical image of a treatment volume irradiated during radiotherapy having a plurality of pixels of information is obtained (*see* Abstract).

Burdette describes a method and apparatus for three-dimensional imaging and treatment of a patient's body. The method and apparatus utilize a system for developing a therapy plan for treatment of an organ of the patient, a device for generating ultrasound image data from a treatment region and a device for providing a translucent volume image of a portion of a patient's body and a separate translucent image of the patient organ and a three dimensional viewing device to superimpose a translucent article image to enable viewing of the article image simultaneously with the patient organ and a portion of the patient's body (*see* Abstract).

Kestin describes a relationship between radiation dose and clinical outcome for prostate cancer. Specifically, Kestin recognizes that the clinical significance of postradiotherapy (RT) prostate biopsy characteristics is not well understood relative to the known prognostic factors. Kestin performs a detailed pathologic review of posttreatment biopsy specimens in an attempt to clarify their relationship with clinical outcome and radiation dose (*see* Abstract and Introduction).

Helmick describes a study that evaluates the variability in dosimetry due to the change in prostate volume for permanent transperineal brachytherapy seed implant. Nineteen cases are retrospectively evaluated. A single physician defined prostate volumes in all cases. Group A consisted of 3 cases that were treated with external-beam radiation therapy (EBRT) to 4500 cGy, followed by a brachytherapy implant boost of 10,800 cGy. Group B included 16 cases that were implant only, prescribed to 14,400 cGy. Prostate images were acquired before seed implant using transrectal ultrasound (TRUS), immediately following seed implant using TRUS, and by computed tomography (CT) acquired several weeks postimplant. The prostate images were digitized into a commercial treatment planning system for planning purposes and dosimetric evaluation for the 3 procedures. Prostate volumes were calculated by the treatment planning system. Additional data collected included the percentage of prostate receiving the prescribed dose and dose to 90% and 80% of the prostate. The dose delivered to V150 was also recorded. Overall, the postimplant ultrasound plan showed similar coverage to the ultrasound preplan, while the CT postplan revealed less than expected dosimetric coverage. The postplan CT results prompted us to evaluate our scheduling process, as well as prostate definition using TRUS and CT (*see* Abstract and Materials and Methods).

Good describes versatile radioactive implants and methods of radiation therapy, plating methods such as sputtering, that are used to coat single elements such as microspheres, wires and ribbons with radioactive metals, protective layers and identification layers. The resulting solid, radioactive, multilayered seamless elements are implanted individually or combined in intercavity applicators, with fabrics and in ribbons. Because they have selected half-lives and intensities, they provide flexibility in treatment, permitting low intensity or high intensity treatment. using temporary or permanent implants and implants with high intensity or low intensity or contoured intensity to permit different therapies (*see* Abstract).

Widener describes methods, systems, devices, and computer program products that include positioning disposable single-use radiation sensor patches that have adhesive means onto the skin of a patient to evaluate the radiation dose delivered during a treatment session. The sensor patches are configured to be minimally obtrusive and operate without the use of externally extending power chords or lead wires (*see* Abstract).

CLAIMS 1, 7 and 9

Independent claim 1 provides a system for processing data concerning patient radiation treatment. An input processor receives data identifying a first radiation dose, received by a particular anatomical part of a patient, from a radiation source external to a patient and a second radiation dose, received by the particular anatomical part of the patient from a radiation source internal to the patient and implanted within the patient. A data processor combines data representing the first and second dose by automatically summing values representing the first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by the particular anatomical part of the patient. A storage processor automatically stores the combined therapeutic dose value in an electronic record associated with the patient in a repository concurrently accessible by a plurality of different healthcare workers using remote devices. A workflow processor schedules and manages a sequence of tasks involved in producing a treatment plan using the electronic record including the combined therapeutic dose value. Wessol, Burdette, Kestin and Helmick, when taken alone or in any combination, do not make the present claimed invention unpatentable.

Wessol, unlike the present claimed invention, provides a method and system for developing a dosimetry plan for a treatment volume irradiated during radiation therapy with a radiation source concentrated internally within a patient **OR** incident from an external beam (*see* Abstract). The Wessol system and method is concerned with providing geometric models of data that will not substantially inhibit the amount of time it takes the system to perform dosimetric calculations to be used with the radiation therapy (*see* col. 3, lines 10-21). The Wessol system geometrically models the amount of radiation and enables a user to increase the dose to be targeted to the specific portion of the patient's anatomy. This is fundamentally different from the present claimed invention which receives data representing dosing information from two radiation sources (one internal to a patient and one external from a patient) to be combined into a single value that is added to a patient record and that is used by "a workflow processor for scheduling and managing a sequence of tasks involved in producing a treatment plan."

Element 26 in Figure 1 of Wessol is a BIOS or Basic Input/Output System that includes "the basic routines that help to transfer information between elements **within the computer 20**, such as during start-up" and which may be stored in a read only memory. This is fundamentally different from, and cannot be reasonably interpreted to be equivalent to, the present claimed input processor. The control of the internal operations of a computer system as in Wessol, is NOT equivalent to an input processor for receiving the data such as claimed in claim 1.

Moreover, Wessol fails to disclose or suggest "a data processor for combining data representing said first and second dose by **automatically summing values representing said first and second dose** to provide a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient" as recited in claim 1 of the present invention. Figure 3 of Wessol describes obtaining information regarding internal and external radiation sources (Fig. 3, 110 and 113). However, the information received by the Wessol regarding radiation from internal and external sources is not "automatically summed" to produce "a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient" as in the present claimed invention. In fact, as stated in column 8, lines 40 – 58 and shown in Figure 3, data representing imagery of the radiation emitted from the internal radiation source is acquired mutually exclusively from the data representing imagery of the radiation emitted from any external radiation source. Moreover, this imagery data obtained and visualized by the Wessol system is from a radiation source that introduces radiation in "concentrations or amounts smaller than required to conformally irradiate the treatment volume, yet large enough to be observed so as to obtain data or information on the irradiation" (col. 8, lines 7-10). Wessol provides for computationally escalating and/or enhancing the respective imagery data to produce a visual depiction regarding the effect the radiation has on a particular body part enabling more precise calculations for changing a treatment plan so as to improve the efficacy thereof (*see* column 8, lines 21-39). There is no mention of automatically combining data from two different radiation sources to come up with a cumulative therapeutic dose as in the feature combination of the present claimed invention.

Additionally, the present claimed invention is concerned with radiation treatment planning using a total amount of radiation that is applied to a particular body part and using the "combined therapeutic dose value" that is stored in a patient record "for scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record." Wessol neither discloses nor suggests this feature. As discussed above, Wessol fails to provide "a combined therapeutic dose value" because Wessol is concerned with a single radiation source that emits an amount of radiation less than therapeutically required but in an amount enabling creation of a radiation image to improve dosage changes for the particular patient on the particular body part. While Wessol provides that the single source may be internal or external from the patient, this is not equivalent to "automatically summing values representing said first and second does" where the first dose is "from a radiation source external to a patient" and the second dose is "received by said particular anatomical part of said patient from a radiation source internal to and implanted within said patient" as recited in the present claimed invention. Thus, while Wessol provides hardware storage elements, there is no mention or suggestion of the claimed "storage processor" that stores the combined value in "an electronic record associated with said patient" and which is "concurrently accessible by a plurality of different healthcare workers" as recited in the present claimed invention. The claimed system uses the combined therapeutic value of radiation to schedule and manage tasks to produce a treatment plan for a patient. Thus, the claimed feature of concurrent access to a storage repository having the combined therapeutic value stored therein advantageously enables multiple different users in different locations access to the information to facilitate creating a patient treatment plan. Wessol does not contemplate this feature because the Wessol system is wholly unrelated to "scheduling and managing a sequence of tasks involved in producing a treatment plan" using a "combined therapeutic dose value" of radiation received from internal and external sources, as in the present claimed invention. Rather, Wessol uses a test amount of radiation to create an image that may be escalated to improve a workers ability to make dosage modifications for the particular patient.

Wessol is concerned with producing geometric models of radioactivity of a radiation source to better understand and see the impact of the radiation on the patient in hopes of improving radioactive therapy. There is no 35 USC 112 compliant enabling disclosure of the claimed "workflow processor" which schedules and manages tasks for use in producing a treatment plan using the electronic record that includes the combined therapeutic dose value. There is no equivalent structure disclosed or suggested by Wessol. The claimed system advantageously acquires a total amount of radiation from multiple sources to electronically document and store a combined value that is used to schedule and manage tasks in patient treatment plan that must also comply with Nuclear Regulatory Commission (NRC) regulations regarding safe levels of radiation. Thus, the combined therapeutic dose value facilitates treatment planning to ensure that, despite irradiation therapy, the patient will be able to safely intermingle with the public (*see* Specification, page 3 line 2-page 4, line 3). Wessol, as discussed above, uses a known amount of radiation from a single radiation source to produce an image that improves the ability of a healthcare worker to change/modify the dose of radiation to be applied to the patient. Wessol is an imaging system that aids in dosage calculations. In contrast, the claimed arrangement uses a "workflow processor" that uses combined therapeutic dose value of radiation from internal and external sources to aid in "scheduling and managing a sequence of tasks involved in producing a treatment plan" for the particular patient. Wessol fails to provide any equivalent structural elements that perform the claimed features.

The Office Action on page 3 agrees that "Wessol et al. does not specifically disclose the use of combined therapeutic dose value of radiation from internal and external sources to aid in scheduling and managing a sequence of tasks involved in producing a treatment plan, and a workflow processor for scheduling and managing a sequence of tasks in producing a treatment plan including the combined dose value." Applicant respectfully submits that Wessol also does not disclose or suggest the other claimed features of the present invention, as argued above. Additionally, Applicant respectfully submits that even if Wessol was combined with Burdette, Kestin and Helmick, the combination would not make the present claimed invention unpatentable.

Burdette describes "carrying out minimally invasive treatments of the human body by virtual reality visualization of the treatment area ... [and] providing real time images of a human anatomy undergoing treatment along with rapid radiation seed therapy planning" (col. 1, lines 11-17). The Office Action on pages 3-4 cites the Abstract, Fig. 1A, col. 4, lines 38-60, col. 2, lines 8-47 and col. 5, lines 17-45 of Burdette as being relevant the present claimed invention. Applicant respectfully disagrees. Nowhere in the cited passages or figures of Burdette is there any mention or suggestion of "a workflow processor for scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record including said combined therapeutic dose value" as recited in claim 1 of the present invention. The Abstract of Burdette describes:

> "three-dimensional imaging and treatment of a patient's body … a system for developing a therapy plan for treatment of an organ of the patient, a device for generating ultrasound image data from a treatment region and a device for providing a translucent volume image of a portion of a patient's body and a separate translucent image of the patient organ and a three dimensional viewing device to superimpose a translucent article image to enable viewing of the article image simultaneously with the patient organ and a portion of the patient's body."

Burdette also describes "computer software for real-time image acquisition, image contouring, dose calculation and display software, dose volume histograms, three-dimensional dose countours, post-implant seed localization" (col. 5, lines 17-21). "The system software enables a two-dimensional and three-dimensional image visualization for brachytherapy employing two-dimensional ultrasound imaging for use in radioactive seed implants of the prostate" (col. 5, lines 24-27).. Furthermore, Burdette describes a

> "transrectal ultrasound guided transperineal implant technique [that] has been developed ... That procedure [for the technique] is described in three steps: (1) the initial volumetric assessment of the prostate gland performed using ultrasound, (2) development of a radiation therapy 'pre-plan,' and (3) performing the actual intraoperative implant. The purpose of the initial volumetric assessment prior to the pre-plan or implantation is to obtain a quantitative understanding of the size of the prostate, which is then used to determine the total activity and distribution of radioactivity which is to be implanted into the prostate. To perform the assessment, an ultrasound probe is physically attached to a template ... Once the three-dimensional contour data has been obtained for the prostate volume, a radiation therapy plan which describes the positions of the radioactive seeds within the prostate is developed. This plan attempts to optimize the dose to the prostate, minimize the dose to surrounding healthy tissue, and minimize dose inhomogeneity. The positions of the radioactive seeds are constrained to fall within the catheter tracks, since the seeds are placed within the prostate transperineally via these catheters. The result of the pre-plan describes the positions and strengths of the radioactive seeds within the catheter which optimizes the dose to the prostate" (col. 2, lines 8-47).

Additionally, cited col. 4, lines 38-60 merely describes

> "[a] three-dimensional probe 12 [that] accumulates image data from a treatment region or organ of a patient, image data is processed using a three-dimensional imaging card ... A conventional personal computer 16 having a monitor can be used to operate on the image data from the imaging card ... Radioactive seeds 18 are provided for insertion ... which may be either needles or stiff catheters ... enabl[ing] a user to visualize a translucent image of the patient organ and real time interaction of any one of a variety of treatment devices, such as the implant needles 19 or a Foley catheter 20, and one of the seeds 18 within the organ. Computer software can be utilized in a conventional manner to visualize the three-dimensional imaging data in various formats" (col. 4, lines 39-61).

Furthermore, cited Fig. 1A is merely a block diagram of a three-dimensional probe. Thus, the cited passages and figures of Burdette describe a brachytherapy system that monitors real-time placement of catheters. Additionally, Burdette describes an automated process "for loading ... radioactive therapeutic treatment seeds based on a clinical plan enabling rapid treatment based on substantially real time pre-planning using rapid patient organ evaluations" (col. 3, lines 47-51). Real or near real time three-dimensional visualization of an organ undergoing treatment is provided. Hence, Burdette provides an improved brachytherapy system that automates the loading of needles/seeds "based upon a pre-plan (dose plan) determined in the operating room (OR)" (col. 10, lines 44-45). However, Burdette neither discloses nor suggests "a workflow processor for **scheduling** and **managing** a sequence of tasks involved in **producing a treatment plan** using said electronic record including said combined therapeutic dose value" as recited in claim 1 of the present invention. Rather, Burdette is only concerned with the automatic loading of needles/seeds in order to view a real time three-dimensional visualization. Therefore, Burdette (with Wessol, Helmick and Kestin) neither discloses nor suggests "a workflow processor for scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record including said combined therapeutic dose value" as recited in claim 1 of the present invention.

Helmick describes a case study conducted with nineteen test patients. The purpose of the study "was to evaluate the variability in dosimetry due to the change in prostate volume for permanent transperineal brachytherapy seed implant" (Abstract). Data was collected from the participants. "A spreadsheet was prepared to record the data collected. It was divided into 3 sections: TRUS preplan data, TRUS postplan data, and CT postplan data" (Materials and Methods, second paragraph). There were two groups of test patients and one patient was excluded from the study. Helmick has separate plans for external beam therapy and brachytherapy. Helmick describes that "Group A consisted of 3 cases that were treated with external-beam radiation therapy ... followed by a brachytherapy implant boost" (Materials and Methods, second paragraph). Therefore, in Helmick, any comparison or calculation is done manually and independently (*see* Fig. 1, "Original" and "Postimplant" values). This is wholly unlike the present claimed invention which **combines** "data representing said first and second dose by **automatically summing values** representing said first and second dose to provide a **combined therapeutic dose value** representing a total cumulative radiation dose received by said particular anatomical part of said patient" as recited in claim 1. Additionally, Helmick nowhere discloses nor suggests "a storage processor for automatically storing said combined therapeutic dose value in an electronic record associated with said patient in a repository concurrently accessible by a plurality of different healthcare workers using remote devices" as recited in claim 1 of the present invention.

Moreover, Helmick is directed towards dosimetric postplans, as recommended by the American Brachytherapy Society (ABS), for every patient after a prostate implant. The study conducted in Helmick concludes that different time intervals for performing CT scans will yield different total doses (*see* Discussion/Conclusion, second paragraph). Furthermore, Helmick concludes that the average coverage of 47% of the glands volume is due to "(a) CT scans taken too early while prostate edema is still influencing dosimetric coverage, and (b) inclusion of periprostatic tissues due to poor visualization of prostate margins … postimplant TRUS studies had an average prostate volume coverage of 74%. Based on this data ... the changes suggested by this work, coverage of 80% of the CT postimplant prostate volume is achievable with our current preplanning and implant technique" (Discussion/Conclusion, fourth and fifth paragraphs). Thus, Helmick is merely concerned with the change in prostate tumor volume at the end of a seed implant. Helmick takes measurements prior to and postplan and digitizes the images/tumor volumes (*see* Fig. 4). Additionally, Helmick concludes that the findings of the volumes treated tested and treated were too small, and that the process used should be changed to include higher percentage volumes. However, Helmick, similar to Burdette and Wessol (with Kestin) neither discloses nor suggests "a workflow processor for **scheduling and managing a sequence of tasks** involved in **producing a treatment plan** using said electronic record including said combined therapeutic dose value" as recited in claim 1 of the present invention.

Kestin describes a study of clinical trial patients with locally advanced prostate cancer that were prospectively treated with external beat RT in combination with high-dose-rate brachytherapy at William Beaumont Hospital and had post-RT biopsy material available for complete pathologic review conducted between 1991 and 1998. The goal of the study was to perform a detailed pathologic review of posttreatment biopsy specimens in an attempt to clarify their relationship with clinical outcomes and radiation doses. Although Kestin performs "a detailed pathologic analysis of all pretreatment and posttreatment biopsy specimens in patients prospectively treated with EBRT and HDR brachytherapy in an attempt to clarify their relationship with clinical outcome and radiation dose" (Introduction, fourth paragraph), Kestin does not disclose or suggest "combining data representing said first and second dose by **automatically summing values** representing said first and second dose to provide a **combined therapeutic dose value** representing a total cumulative radiation dose received by said particular anatomical part of said patient" as recited in claim 1 of the present invention. Rather, Kestin is only concerned with pre-radiotherapy and posttreatment biopsy characteristics to determine if tissue samples taken were cancer free, as described in the "Results" section and Tables. Therefore, Kestin neither discloses nor suggests "a data processor for combining data representing said first and second dose by **automatically summing values** representing said first and second dose to provide a **combined therapeutic dose value** representing a total cumulative radiation dose received by said particular anatomical part of said patient" or "a storage processor for **automatically storing** said combined therapeutic dose value in an electronic record associated with said patient in a repository concurrently accessible by a plurality of different healthcare workers using remote devices" as recited in claim 1 of the present invention.

Additionally, Applicant respectfully disagrees with the assertion made by the Office Action that Kestin "teaches a medical treatment system for the application of radiation treatment planning using the combined therapeutic dose value of radiation from internal and external sources to aid in scheduling and managing a sequence of tasks involved in producing a treatment plan, and having a workflow processor for scheduling and managing a sequence of tasks in producing a treatment plan including the combined dose value." The study performed in Kestin is concerned with external beam radiotherapy (EBRT) and brachytherapy, however, Kestin does not disclose or suggest "automatically summing values representing said first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient" as recited in claim 1 of the present invention. Also, as Kestin is concerned with pre-radiotherapy biopsy measurements and posttreatment biopsy characteristics and not with the "**scheduling and managing**" of "a sequence of tasks involved in producing a **treatment plan** using said electronic record including said combined therapeutic dose value" as recited in claim 1 of the present invention.

Furthermore, Applicant respectfully submits that a combination of Wessol, Burdette, Helmick and Kestin, as suggested by the Office Action would not be obvious for a person of ordinary skill in the art and would not produce an operable device. Wessol is directed towards real time three-dimensional models of patient body parts analytically computing dosimetry plans for use in radiotherapy planning. Burdette is concerned with virtual reality visualization of a patient's treatment area. Helmick and Kestin, which are completely unrelated to Wessol and Burdette, merely describe the results of a studies performed for calculating the volumes of tumors before and after a treatment. Therefore, it would no be obvious to combine the systems of Wessol and Burdette with the clinical studies of Helmick and Kestin.

There is no teaching in any of the references of how these disparate (and at least partially incompatible) systems may be operably combined. However, even if the systems and studies of Wessol, Burdette, Helmick and Kestin could be combined, such a combination would not make the present claimed invention unpatentable. The combination would merely yield a system capable of measuring data and recording three-dimensional images of a cancerous area of a patient's body before and after external beam radiation and brachytherapy. The images would be provided in real-time. However, the combined system does not store a "combined therapeutic value" which represents "a total cumulative radiation dose received by said particular anatomical part of said patient" in "an electronic record associated with said patient in a repository concurrently accessible by a plurality of different healthcare workers using remote devices" as recited in claim 1 of the present invention. Although the combined system may describe a radiation therapy plan, the combined system neither discloses nor suggests "a workflow processor for scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record including said combined therapeutic dose value" as recited in claim 1 of the present invention. Therefore, the combined system does not make the present claimed invention unpatentable.

Therefore, as Wessol, Burdette, Helmick and Kestin fail to show or suggest each feature in claim 1, Wessol, Burdette, Helmick and Kestin, when taken alone or in any combination, do not make the present claimed invention unpatentable. Additionally, as claims 7 and 9 are dependent on independent claim 1, these claims are allowable over Wessol, Burdette, Helmick and Kestin. Consequently, it is respectfully requested that the rejection of claims 1, 7 and 9 under 35 U.S.C. 103(a) be withdrawn.

CLAIM 3

Claim 3 is dependent on claim 1 and is considered patentable for the reasons presented above with respect to claim 1. Claim 3 is also considered patentable because Wessol, Burdette, Helmick and Kestin neither disclose nor suggest that the "data processor **automatically populates** a patient radiation survey record form with data derived from radiation survey equipment indicating radiation levels **emitted by a patient**" as recited in claim 3 of the present invention. The combined system of Wessol, Burdette, Helmick and Kestin is only concerned with using medical imaging devices such as MRIs, etc. to generate a real-time geometric model of the radioactivity of a particular **radiation source** to improve the view in order to change the dosing thereof. The combined system is not concerned with a "data processor [that] **automatically populates** a patient radiation survey record form with data derived from **radiation survey equipment indicating radiation levels** emitted by a patient" as recited in claim 3 of the present invention. Rather, the combined system merely creates an image to improve dosage calculations for targeted radiation therapy for a patient and performs calculations of effects of radiation on a volume of a patient's prostate. This is fundamentally different from the claimed system because the claimed system facilitates treatment and planning of radiation therapy that complies with NRC safety regulations by surveying and automatically populating a total amount of radiation emitted by internal and external radiation sources and also emitted by the patient. Thus, the combined system, similar to the individual systems of Wessol, Burdette, Helmick and Kestin, neither discloses nor suggest a "data processor [that] automatically populates a patient radiation survey record form with data derived from radiation survey equipment indicating radiation levels emitted by a patient" as recited in claim 3 of the present invention.

Therefore, as Wessol, Burdette, Helmick and Kestin fail to show or suggest each feature in claim 3, Wessol, Burdette, Helmick and Kestin, when taken alone or in any combination, do not make the present claimed invention unpatentable. Consequently, it is respectfully requested that the rejection of claim 3 under 35 U.S.C. 103(a) be withdrawn.

CLAIM 11

Claim 11 is dependent on claim 1 and is considered patentable for the reasons presented above with respect to claim 1. Claim 11 is also considered patentable because Wessol, Burdette, Helmick and Kestin neither disclose nor suggest "an interface processor for using said combined therapeutic dose value in configuring a radiation therapy device for delivering a radiation treatment to a patient" as recited in claim 11 of the present invention. The combined system of Wessol, Burdette, Helmick and Kestin provides that the geometric three-dimensional image modeling may be performed by any computing device. Although the combined system may describe a virtual reality interface system, the system is only used to view dose pre-plan information prior to loading a seed into a patient. However, this is not equivalent to "an interface processor for using said combined therapeutic dose value in configuration of a radiation therapy device for delivering a radiation treatment to a patient" as recited in claim 11 of the present invention.

Therefore, as Wessol, Burdette, Helmick and Kestin fail to show or suggest each feature in claim 11, Wessol, Burdette, Helmick and Kestin, when taken alone or in any combination, do not make the present claimed invention unpatentable. Consequently, it is respectfully requested that the rejection of claim 11 under 35 U.S.C. 103(a) be withdrawn.

In view of the above remarks, Applicant respectfully submits that Wessol, Burdette, Helmick and Kestin, when taken alone or in any combination, do not make the present claimed invention unpatentable. Therefore, Applicant further respectfully submits that this rejection has been satisfied and should be withdrawn.

Rejection of claims 2, 4-6, 8 10 and 12-14 under 35 U.S.C. 103(a) over Wessol (U.S. Patent No. 6,965,847), in view of Burdette (U.S. Patent No. 6,129,670), in view of Kestin *"Pathologic Evidence of Dose-Response and Dose-Volume Relationships for Prostate Cancer Treated with Combined External Beam Radiotherapy and High-Dose-Rate Brachytherarpy,"* in view of Helmick *"Evaluation of Post-Plan Dosimetery Using TRUS and CT After*

Transperineal Prostate Seed Implant," in view of Good (U.S. Patent No. 6,099,457) and in further view of Widener (U.S. Patent Pub. No. 2004/0236207)

Reversal of the rejection of claims 2, 4-6, 8 10 and 12-14 under 35 U.S.C. 103(a) as being unpatentable over Wessol (U.S. Patent No. 6,965,847), in view of Burdette (U.S. Patent No. 6,129,670), in view of Kestin *"Pathologic Evidence of Dose-Response and Dose-Volume Relationships for Prostate Cancer Treated with Combined External Beam Radiotherapy and High-Dose-Rate Brachytherarpy,"* in view of Helmick *"Evaluation of Post-Plan Dosimetery Using TRUS and CT After Transperineal Prostate Seed Implant,"* in further view of Good (U.S. Patent No. 6,099,457) and in further view of Widener (U.S. Patent Pub. No. 2004/0236207) is respectfully requested because the rejection makes crucial errors in interpreting the cited reference. The rejection erroneously states that claims 2, 4-6, 8 10 and 12-14 are made unpatentable by Wessol in view of Burdette, in view of Kestin, in view of Helmick, in view of Good and in further view of Widener.

CLAIMS 2, 5, 6 and 10

Claim 2 is dependent on claim 1 and is considered patentable for the reasons presented above with respect to claim 1. Claim 2 is also considered patentable because Wessol, Burdette, Helmick and Kestin (with Good and/or Widener) fail to disclose or suggest that the "input processor automatically acquires patient radiation survey record data from radiation survey equipment indicating radiation levels emitted by a patient" and that the "storage processor stores said acquired patient radiation survey record data in said repository" as recited in claim 2 of the present invention. For the reasons presented below, Good and Widener, when combined with Wessol, Burdette, Helmick and Kestin, do not make the present invention as claimed in claims 1 or 2 unpatentable.

Good provides a method for making radioactive spheres that may be used in radioactive therapy and treatment of a patient (*see* Abstract). This is fundamentally different from the present claimed system which seeks to monitor radioactive doses from different radioactive sources and which utilizes a "workflow processor" to schedule and manage a sequence of tasks involved in producing a treatment plan that takes into account the stored "combined therapeutic dose value" of radiation already received by the patient. The Office Action on pages 6-7 cites col. 3, lines 4-11 and col. 5, lines 39-47 of Good in support of the assertion that Good discloses the automatic summation of dose values claimed in the present invention. Applicant respectfully disagrees. Rather, the section of col. 3 cited merely describes producing an implantable radioactive device that delivers high energy irradiation to a tumor site. There is nothing in this section (or elsewhere) of Good that discloses or suggests "automatically summing values representing said first and second dose to provide a combined therapeutic dose value" as recited in the present claimed system. The description in col. 5 of Good also adds nothing that could allow one to reasonably conclude that Good discloses the automatic summation feature of the present claimed system. Instead the cited section of Good merely describes how the implant hopes to affect a cancer cell by releasing radiation. Good is wholly unlike and unrelated to the present claimed invention as Good merely describes producing a source of radiation that may be monitored using the claimed system.

Widener provides a surface mount radiation dosimeter that is able to evaluate the radiation dosage applied to a patient that is undergoing radiation therapy. These patches are applied to a patient and the dosage of radiation over each patch can be sensed and calculated. Thus, Widener is concerned with an external device used to monitor radiation delivered. Widener includes a disposable monitor which is attached to the patient and a reading device. A storage device stores the collected data and the data can be queried. The dose reader may utilize wireless technology. Widener may provide a mechanism to capture information regarding the dose of radiation, however, Widener fails to disclose or suggest producing a "combined therapeutic dose value" that is used by a "workflow processor for scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record" which has the combined therapeutic dose value stored therein, as recited in the present claimed invention. The present claimed invention, contrary to Widener, provides a fully integrated radiation treatment record. Widener, nowhere in the cited passages or figures discloses or suggests the features of the present claimed invention.

Additionally, Good and Widener (with Wessol, Burdette, Kestin and Helmick) are not at all concerned with automatically acquiring data from radiation **survey** equipment corresponding to an amount of radiation **emitted** by a patient. Rather, each of these systems, when taken alone or in any combination with one another, are concerned with entirely unrelated problems. Wessol merely creates an image to improve targeted radiation therapy for a patient. Burdette is concerned with virtual reality visualization of a patient's treatment area. Helmick and Kestin, which are completely unrelated to Wessol, Burdette, Good and Widener, merely describe the results of a studies performed for calculating the volumes of tumors before and after a treatment. Good describes how to produce a radiation source and Widener provides patches that may be used to measure radiation over a particular area on the body. This is fundamentally different from the claimed system because the claimed system facilitates treatment and planning of radiation therapy that complies with NRC safety regulations by surveying a total amount of radiation emitted by internal and external radiation sources and also emitted by the patient. Good and Widener, Wessol, Burdette, Kestin and Helmick provide no 35 USC 112 compliant enabling disclosure of these features.

Applicant respectfully submits that there is no motivation to combine any of the six systems and patient clinical studies. Wessol, Burdette, Kestin, Helmick, Good and Widener as they are all in fundamentally different areas of art. Specifically, Wessol is concerned with providing a geometric model of radiation applied to a patient to improve the view of how the radiation affects the patient. Burdette is concerned with virtual reality visualization of a patient's treatment area. Widener provides a patch that senses the amount of radiation being applied to a patient and Good provides a method for producing a source of the radiation used to treat a patient. Helmick and Kestin describe the results of a studies performed for calculating the volumes of tumors before and after a treatment. These references provide unrelated apparatus and clinical studies that each accomplishes entirely unrelated objectives. There would be no reason to combine an implantable device for emitting radioactive therapy (as in Good) with a system such as Wessol which computationally models the emitted radiation with respect to the body to aide in modifying the dosage of radiation used in treatment of the patient, with the studies performed by Helmick and Kestin. Moreover, a person of ordinary skill in the art would not find it obvious to combine all six references. Therefore, Applicant respectfully submits that there is no reason or motivation to combine these references.

Additionally, even if one were to combine these references, the result would not produce a system equivalent to the present claimed invention. The system resulting from the combination of Wessol, Burdette, Helmick, Kestin Good and Widener would not be structurally or functionally equivalent to the present claimed system. The combination neither discloses nor suggests a "combined therapeutic dose value" that is used by a "workflow processor for scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record" which has the combined therapeutic dose value stored therein. Rather, the combination would merely yield a system capable of measuring data and recording three-dimensional images of a cancerous area of a patient's body before and after external beam radiation and brachytherapy. The images would be provided in real-time. A patch would be included that senses the amount of radiation being applied to a patient. The radioactive implants used would be mass produced and versatile. However, the combination would not disclose or suggest the claimed features of the present invention.

Therefore, as Wessol, Burdette, Helmick, Kestin, Good and Widener fail to show or suggest each feature in claims 1 and 2, Wessol, Burdette, Helmick, Kestin, Good and Widener, when taken alone or in any combination, do not make the present claimed invention unpatentable. Additionally, as claims 5, 6 and 10 are dependent upon claim 1, these claims are also not made unpatentable by Wessol, Burdette, Helmick, Kestin, Good and Widener. Consequently, it is respectfully requested that the rejection of claims 2, 5, 6 and 10 under 35 U.S.C. 103(a) be withdrawn.

CLAIM 4

Claim 4 is dependent on claim 1 and considered patentable for the reasons presented above with respect to claims 1 and 2. Claim 4 is also considered patentable because Wessol, Burdette, Helmick, Kestin, Good and Widener fail to disclose or suggest "a rules processor for initiating generation of an alert message for communication to a healthcare worker, in response to said combined therapeutic dose value and automatically initiating generation of an alert message for communication to a healthcare worker, in response to determining inappropriate **radiation settings of a radiation imaging or therapy device** in response to said combined therapeutic dose value" as recited in claim 4 of the present invention. There is no mention in any of Wessol, Burdette, Helmick, Kestin, Good and Widener of determining that a level of radiation to be emitted by a device is inappropriate in view of a combined therapeutic dose value and automatically generating an alert message in response thereto. These systems, as discussed above, are fundamentally different from the present claimed invention. Unlike Good, Widener, Wessol, Burdette, Helmick and Kestin, the present claimed invention provides a system that aids in complying with government guidelines associated with radioactive methods of patient treatment. Specifically, the claimed system includes a "rules processor" that interacts with radiation imaging and/or therapy devices and determines if settings of the device are "inappropriate" in view of the combined therapeutic dose value. Thus, the claimed system advantageously controls tasks associated with a treatment plan and ensures compliance with NRC guidelines by using a combined therapeutic dose value applied to a patient to check the settings on the radiation device to make sure they are within acceptable levels.

Therefore, as Wessol, Burdette, Helmick, Kestin, Good and Widener fail to show or suggest each feature in claims 1 and 4, Wessol, Burdette, Helmick, Kestin, Good and Widener, when taken alone or in any combination, do not make the present claimed invention unpatentable. Consequently, it is respectfully requested that the rejection of claim 4 under 35 U.S.C. 103(a) be withdrawn.

CLAIM 8

Claim 8 is dependent on claim 1 and is considered patentable for the reasons presented above with respect to claim 1. Claim 8 is also considered patentable because Wessol, Burdette, Helmick, Kestin, Good and Widener fail to disclose or suggest "a communication interface for initiating communication of an alert message to a user identifying said combined therapeutic dose value" as recited in claim 8 of the present invention. Wessol, Burdette, Helmick, Kestin, Good and Widener use known amounts of radiation to generate a three-dimensional image. The amount of radiation would not be at a level that would require alerting any personnel using the systems of Wessol, Burdette, Helmick, Kestin, Good and Widener. Additionally, there would be no reason or motivation to include this feature in any of these references.

Therefore, as Wessol, Burdette, Helmick, Kestin, Good and Widener fail to show or suggest each feature in claim 8, Wessol, Burdette, Helmick, Kestin, Good and Widener, when taken alone or in any combination, do not make the present claimed invention unpatentable. Consequently, it is respectfully requested that the rejection of claim 8 under 35 U.S.C. 103(a) be withdrawn.

CLAIM 12

Independent claim 12 provides a system for processing data concerning patient radiation treatment. An input processor receives data identifying a first radiation dose received by a particular anatomical part of a patient, from a radiation source external to a patient. A second radiation dose is received by the particular anatomical part of the patient from the radiation source internal to the patient and implanted within the patient. A data processor combines data representing the first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by the particular anatomical part of the patient. A rules processor is included for automatically initiating generation of an alert message for communication to a healthcare worker, in response to determining inappropriate radiation settings of a radiation imaging or therapy device in response to the combined therapeutic dose value. A storage processor automatically stores the combined therapeutic dose value in an electronic record associated with the patient in a repository concurrently accessible by a plurality of healthcare workers using remote devices. A task manager updates a record indicating a task to be performed by including an additional task in response to the combined therapeutic dose value. Wessol, Burdette, Kestin, Helmick, Good and Widener, when taken alone or in any combination, do not make the present claimed invention unpatentable.

Wessol, unlike the present claimed invention, provides a method and system for developing a dosimetry plan for a treatment volume irradiated during radiation therapy with a radiation source concentrated internally within a patient **OR** incident from an external beam (*see* Abstract). The Wessol system and method is concerned with providing geometric models of data that will not substantially inhibit the amount of time it takes the system to perform dosimetric calculations to be used with the radiation therapy (*see* col. 3, lines 10-21). The Wessol system geometrically models the amount of radiation and enables a user to increase the dose to be targeted to the specific portion of the patient's anatomy. This is fundamentally different from the present claimed invention which receives data representing dosing information from two radiation sources (one internal to a patient and one external from a patient) to be combined into a single value that is added to a patient record and that is used by "a task manager for updating a record indicating a task to be performed by including an additional task in response to said combined therapeutic dose value."

Moreover, Wessol fails to disclose or suggest "combining data representing said first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient and including a rules processor for **automatically initiating generation** of an alert message for communication to a healthcare worker, in response to determining inappropriate radiation settings of a radiation imaging or therapy device in response to said combined therapeutic dose value" as recited in claim 12 of the present invention. The Office Action agrees with this on pages 3 and 5. Additionally, Applicant respectfully submits that even if Wessol was combined with Burdette, Kestin, Helmick, Good and Widener, the combination would not make the present claimed invention unpatentable.

Burdette describes "carrying out minimally invasive treatments of the human body by virtual reality visualization of the treatment area ... [and] providing real time images of a human anatomy undergoing treatment along with rapid radiation seed therapy planning" (col. 1, lines 11-17). Nowhere in the Burdette is there any mention or suggestion of "a task manager for updating a record indicating a task to be performed by including an additional task in response to said combined therapeutic dose value" as recited in claim 12 of the present invention. Burdette describes "computer software for real-time image acquisition, image contouring, dose calculation and display software, dose volume histograms, three-dimensional dose contours, post-implant seed localization" (col. 5, lines 17-21). "The system software enables a two-dimensional and three-dimensional image visualization for brachytherapy employing two-dimensional ultrasound imaging for use in radioactive seed implants of the prostate" (col. 5, lines 24-27).. Furthermore, Burdette describes a

> "transrectal ultrasound guided transperineal implant technique [that] has been developed ... That procedure [for the technique] is described in three steps: (1) the initial volumetric assessment of the prostate gland performed using ultrasound, (2) development of a radiation therapy 'pre-plan,' and (3) performing the actual intraoperative implant. The purpose of the initial volumetric assessment prior to the pre-plan or implantation is to obtain a quantitative understanding of the size of the prostate, which is then used to determine the total activity and distribution of radioactivity which is to be implanted into the prostate. To perform the assessment, an ultrasound probe is physically attached to a template ... Once the three-dimensional contour data has been obtained for the prostate volume, a radiation therapy plan which describes the positions of the radioactive seeds within the prostate is developed. This plan attempts to optimize the dose to the prostate, minimize the dose to surrounding healthy tissue, and minimize dose in homogeneity. The positions of the radioactive seeds are constrained to fall within the catheter tracks, since the seeds are placed within the prostate transperineally via these catheters. The result of the pre-plan describes the positions and strengths of the radioactive seeds within the catheter which optimizes the dose to the prostate" (col. 2, lines 8-47).

Additionally, col. 4, lines 38-60 merely describes

> "[a] three-dimensional probe 12 [that] accumulates image data from a treatment region or organ of a patient, image data is processed using a three-dimensional imaging card ... A conventional personal computer 16 having a monitor can be used to operate on the image data from the imaging card ... Radioactive seeds 18 are provided for insertion ... which may be either needles or stiff catheters ... enabl[ing] a user to visualize a translucent image of the patient organ and real time interaction of any one of a variety of treatment devices, such as the implant needles 19 or a Foley catheter 20, and one of the seeds 18 within the organ. Computer software can be utilized in a conventional manner to visualize the three-dimensional imaging data in various formats" (col. 4, lines 39-61).

Furthermore, Fig. 1A is merely a block diagram of a three-dimensional probe. Thus, Burdette describe a brachytherapy system that monitors real-time placement of catheters. Additionally, Burdette describes an automated process "for loading … radioactive therapeutic treatment seeds based on a clinical plan enabling rapid treatment based on substantially real time pre-planning using rapid patient organ evaluations" (col. 3, lines 47-51). Real or near real time three-dimensional visualization of an organ undergoing treatment is provided. Hence, Burdette provides an improved brachytherapy system that automates the loading of needles/seeds "based upon a pre-plan (dose plan) determined in the operating room (OR)" (col. 10, lines 44-45). However, Burdette neither discloses nor suggests "**automatically initiating generation** of an **alert message** for communication to a healthcare worker, in response to determining inappropriate radiation settings of a radiation imaging or therapy device in response to said combined therapeutic dose value" and "a task manager for **updating a record** indicating a task to be performed by including an additional task in response to said combined therapeutic dose value" as recited in claim 12 of the present invention. Rather, Burdette is only concerned with the automatic loading of needles/seeds in order to view a real time three-dimensional visualization. Therefore, Burdette (with Wessol, Helmick, Kestin, Good and Widener) neither discloses nor suggests the features of the present claimed invention.

Helmick describes a case study conducted with nineteen test patients. The purpose of the study "was to evaluate the variability in dosimetry due to the change in prostate volume for permanent transperineal brachytherapy seed implant" (Abstract). Data was collected from the participants. "A spreadsheet was prepared to record the data collected. It was divided into 3 sections: TRUS preplan data, TRUS postplan data, and CT postplan data" (Materials and Methods, second paragraph). There were two groups of test patients and one patient was excluded from the study. Helmick has separate plans for external beam therapy and brachytherapy. Helmick describes that "Group A consisted of 3 cases that were treated with external-beam radiation therapy ... followed by a brachytherapy implant boost" (Materials and Methods, second paragraph). Therefore, in Helmick, any comparison or calculation is done manually and independently (*see* Fig. 1, "Original" and "Postimplant" values). This is wholly unlike the present claimed invention which **combines** "data representing said first and second dose to provide a **combined therapeutic dose value** representing a total cumulative radiation dose received by said particular anatomical part of said patient and including a rules processor for automatically initiating generation of an alert message for communication to a healthcare worker, in response to determining inappropriate radiation settings of a radiation imaging or therapy device in response to said combined therapeutic dose value" as recited in claim 12. Additionally, Helmick nowhere discloses nor suggests "a storage processor for automatically storing said combined therapeutic dose value in an electronic record associated with said patient in a repository concurrently accessible by a plurality of healthcare workers using remote devices" as recited in claim 12 of the present invention.

Moreover, Helmick is directed towards dosimetric postplans, as recommended by the American Brachytherapy Society (ABS), for every patient after a prostate implant. The study conducted in Helmick concludes that different time intervals for performing CT scans will yield different total doses (*see* Discussion/Conclusion, second paragraph). Furthermore, Helmick concludes that the average coverage of 47% of the glands volume is due to "(a) CT scans taken too early while prostate edema is still influencing dosimetric coverage, and (b) inclusion of periprostatic tissues due to poor visualization of prostate margins … postimplant TRUS studies had an average prostate volume coverage of 74%. Based on this data ... the changes suggested by this work, coverage of 80% of the CT postimplant prostate volume is achievable with our current preplanning and implant technique" (Discussion/Conclusion, fourth and fifth paragraphs). Thus, Helmick is merely concerned with the change in prostate tumor volume at the end of a seed implant. Helmick takes measurements prior to and postplan and digitizes the images/tumor volumes (*see* Fig. 4). Additionally, Helmick concludes that the findings of the volumes treated tested and treated were too small, and that the process used should be changed to include higher percentage volumes. However, Helmick, similar to Burdette and Wessol (with Kestin, Good and Widener) neither discloses nor suggests "a task manager for **updating a record** indicating a task to be performed by including an additional task in response to said combined therapeutic dose value" as recited in claim 12 of the present invention.

Kestin describes a study of clinical trial patients with locally advanced prostate cancer that were prospectively treated with external beat RT in combination with high-dose-rate brachytherapy at William Beaumont Hospital and had post-RT biopsy material available for complete pathologic review conducted between 1991 and 1998. The goal of the study was to perform a detailed pathologic review of posttreatment biopsy specimens in an attempt to clarify their relationship with clinical outcomes and radiation doses. Although Kestin performs "a detailed pathologic analysis of all pretreatment and posttreatment biopsy specimens in patients prospectively treated with EBRT and HDR brachytherapy in an attempt to clarify their relationship with clinical outcome and radiation dose" (Introduction, fourth paragraph), Kestin does not disclose or suggest "combining data representing said first and second dose to provide a **combined therapeutic dose** value representing a total cumulative radiation dose received by said particular anatomical part of said patient and including a rules processor for **automatically initiating generation** of an **alert message** for communication to a healthcare worker, in response to determining inappropriate radiation settings of a radiation imaging or therapy device in response to said combined therapeutic dose value" as recited in claim 12 of the present invention. Rather, Kestin is only concerned with pre-radiotherapy and posttreatment biopsy characteristics to determine if tissue samples taken were cancer free, as described in the "Results" section and Tables. Therefore, Kestin neither discloses nor suggests "a data processor for combining data representing said first and second dose to provide a combined therapeutic dose value representing a **total cumulative radiation dose** received by said particular anatomical part of said patient and including a rules processor for automatically initiating generation of an alert message for communication to a healthcare worker, in response to determining inappropriate radiation settings of a radiation imaging or therapy device in response to said combined therapeutic dose value" or "a storage processor for **automatically storing** said combined therapeutic dose value in an electronic record associated with said patient in a repository concurrently accessible by a plurality of healthcare workers using remote devices" as recited in claim 12 of the present invention.

Additionally, the study performed in Kestin is concerned with external beam radiotherapy (EBRT) and brachytherapy, however, Kestin does not disclose or suggest "a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient" as recited in claim 12 of the present invention. Also, as Kestin is concerned with pre-radiotherapy biopsy measurements and posttreatment biopsy characteristics and not with "a task manager for **updating** a record indicating a task to be performed by including an additional task in response to said combined therapeutic dose value" as recited in claim 12 of the present invention.

Good provides a method for making radioactive spheres that may be used in radioactive therapy and treatment of a patient (*see* Abstract). This is fundamentally different from the present claimed system which seeks to monitor radioactive doses from different radioactive sources and which utilizes "a task manager for updating a record indicating a task to be performed by including an additional task in response to said combined **therapeutic dose value**" of radiation already received by the patient. Good merely describes mass producing an economical implantable radioactive device, in various shapes, sizes, coverings, and energies in a cost effective manner where the plant delivers high energy irradiation to a tumor site. Good also describes how the implant hopes to affect a cancer cell by releasing radiation. Good is wholly unlike and unrelated to the present claimed invention as Good merely describes producing a source of radiation that may be monitored using the claimed system.

Widener provides a surface mount radiation dosimeter that is able to evaluate the radiation dosage applied to a patient that is undergoing radiation therapy. These patches are applied to a patient and the dosage of radiation over each patch can be sensed and calculated. Thus, Widener is concerned with an external device used to monitor radiation delivered. Widener includes a disposable monitor which is attached to the patient and a reading device. A storage device stores the collected data and the data can be queried. The dose reader may utilize wireless technology. Widener may provide a mechanism to capture information regarding the dose of radiation, however, Widener fails to disclose or suggest producing a "combined therapeutic dose value" that is used by a "a task manager for updating a record indicating a task to be performed by including an additional task in response to" the combined therapeutic dose value stored therein, as recited in the present claimed invention. Additionally, Widener does not automatically store data in an electronic patient record, as in the present claimed invention. The present claimed invention, contrary to Widener, provides a fully integrated radiation treatment record. Widener, nowhere in the cited passages or figures discloses or suggests the features of the present claimed invention.

Additionally, Good and Widener (with Wessol, Burdette, Kestin and Helmick) are not at all concerned with "automatically initiating generation of an alert message for communication to a healthcare worker, in response to determining inappropriate radiation settings of a radiation imaging or therapy device in response to said combined therapeutic dose value" as recited in claim 12 of the present invention. Rather, each of these systems, when taken alone or in any combination with one another, are concerned with entirely unrelated problems. Wessol merely creates an image to improve targeted radiation therapy for a patient. Burdette is concerned with virtual reality visualization of a patient's treatment area. Helmick and Kestin, which are completely unrelated to Wessol, Burdette, Good and Widener, merely describe the results of a studies performed for calculating the volumes of tumors before and after a treatment. Good describes how to produce a radiation source and Widener provides patches that may be used to measure radiation over a particular area on the body. This is fundamentally different from the claimed system because the claimed system facilitates treatment and planning of radiation therapy that complies with NRC safety regulations by surveying a total amount of radiation emitted by internal and external radiation sources and also emitted by the patient. Good, Widener, Wessol, Burdette, Kestin and Helmick provide no 35 USC 112 compliant enabling disclosure of these features.

Applicant respectfully submits that there is no motivation to combine any of the six systems and patient clinical studies. Wessol, Burdette, Kestin, Helmick, Good and Widener as they are all in fundamentally different areas of art. Specifically, Wessol is concerned with providing a geometric model of radiation applied to a patient to improve the view of how the radiation affects the patient. Burdette is concerned with virtual reality visualization of a patient's treatment area. Widener provides a patch that senses the amount of radiation being applied to a patient and Good provides a method for producing a source of the radiation used to treat a patient. Helmick and Kestin describe the results of a studies performed for calculating the volumes of tumors before and after a treatment. These references provide unrelated apparatus and clinical studies that each accomplishes entirely unrelated objectives. There would be no reason to combine an implantable device for emitting radioactive therapy (as in Good) with a system such as Wessol which computationally models the emitted radiation with respect to the body to aide in modifying the dosage of radiation used in treatment of the patient, with the studies performed by Helmick and Kestin. Moreover, a person of ordinary skill in the art would not find it obvious to combine all six references. Therefore, Applicant respectfully submits that there is no reason or motivation to combine these references.

Additionally, even if one were to combine these references, the result would not produce a system equivalent to the present claimed invention. The system resulting from the combination of Wessol, Burdette, Helmick, Kestin Good and Widener would not be structurally or functionally equivalent to the present claimed system. The combination neither discloses nor suggests a "combined therapeutic dose value" that is used by a "a task manager for updating a record indicating a task to be performed by including an additional task in response to said **combined therapeutic dose value**" which has the combined therapeutic dose value stored therein. Rather, the combination would merely yield a system capable of measuring data and recording three-dimensional images of a cancerous area of a patient's body before and after external beam radiation and brachytherapy. The images would be provided in real-time. A patch would be included that senses the amount of radiation being applied to a patient. The radioactive implants used would be mass produced and versatile. However, the combined system does not store a "combined therapeutic dose value" which represents "a total cumulative radiation dose received by said particular anatomical part of said patient" in "an electronic record associated with said patient in a repository concurrently accessible by a plurality of healthcare workers using remote devices" as recited in claim 12 of the present invention. Although the combined system may describe a radiation therapy plan, the combined system neither discloses nor suggests "a **task manager** for updating a record indicating a task to be performed by including an additional task in response to said combined therapeutic dose value" as recited in claim 12 of the present invention. Therefore, the combined system does not make the present claimed invention unpatentable.

Therefore, as Wessol, Burdette, Helmick, Kestin, Good and Widener fail to show or suggest each feature in claim 12, Wessol, Burdette, Helmick, Kestin, Good and Widener, when taken alone or in any combination, do not make the present claimed invention unpatentable. Consequently, it is respectfully requested that the rejection of claim 12 under 35 U.S.C. 103(a) be withdrawn.

Claims 15 and 16 are not specifically rejected to in the Office Action under 35 USC 103(a). However, Applicant respectfully submits that these claims are dependent on claim 12 and are considered patentable over Wessol, Burdette, Helmick, Kestin, Good and Widener, when taken alone or in any combination.

CLAIM 13

Claim 13 is dependent on claim 12 and is considered patentable for the reasons presented above with respect to claim 12. Claim 13 is also considered patentable because Wessol, Burdette, Helmick, Kestin, Good and Widener fail to disclose or suggest updating "a record to indicate a perimeter is to be designated identifying an area around said patient to be avoided by other personnel, in response to said combined therapeutic dose value" as recited in claim 13 of the present invention. As discussed above, the claimed system facilitates compliance with NRC guidelines to ensure that the amount of radiation received by a patient does not exceed levels that are unsafe for the general population. Thus, the claimed system updates a patient record to notify healthcare personnel of an area that needs to be avoided in response to the combined therapeutic dose value calculated for the particular patient. Wessol, Burdette, Helmick, Kestin, Good and Widener are merely concerned with using a known lesser amount of radioactive material to create a three-dimensional image that enables improved targeting for the radiation therapy by allowing a user to change or modify dosage levels based on the images created. This is fundamentally different from and not equivalent to the present claimed system.

Therefore, as Wessol, Burdette, Helmick, Kestin, Good and Widener fail to show or suggest each feature in claim 13, Wessol, Burdette, Helmick, Kestin, Good and Widener, when taken alone or in any combination, do not make the present claimed invention unpatentable. Consequently, it is respectfully requested that the rejection of claim 13 under 35 U.S.C. 103(a) be withdrawn.

CLAIM 14

Independent claim 14 provides a method for processing data concerning patient radiation treatment. Data identifying a first radiation dose, received by a particular anatomical part of a patient, from a radiation source external to a patient is received. A second radiation source, received by the particular anatomical part of the patient from a radiation source internal to the patient and implanted within the patient, is provided. Data representing the first and second dose is combined by automatically summing values representing the first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by the particular anatomical part of the patient. The combined therapeutic dose value is automatically stored in an electronic record associated with the patient in a repository concurrently accessible by a plurality of healthcare workers using remote devices. A sequence of tasks involved in producing a treatment plan are scheduled and managed using the electronic record including the combined therapeutic dose value. Wessol, Burdette, Kestin, Helmick, Good and Widener, when taken alone or in any combination, do not make the present claimed invention unpatentable.

Wessol, unlike the present claimed invention, provides a method and system for developing a dosimetry plan for a treatment volume irradiated during radiation therapy with a radiation source concentrated internally within a patient **OR** incident from an external beam (*see* Abstract). The Wessol system and method is concerned with providing geometric models of data that will not substantially inhibit the amount of time it takes the system to perform dosimetric calculations to be used with the radiation therapy (*see* col. 3, lines 10-21). The Wessol system geometrically models the amount of radiation and enables a user to increase the dose to be targeted to the specific portion of the patient's anatomy. This is fundamentally different from the present claimed invention which receives data representing dosing information from two radiation sources (one internal to a patient and one external from a patient) to be combined into a single value that is added to a patient record and that is used when "scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record including said combined therapeutic dose value."

Moreover, Wessol fails to disclose or suggest "combining data representing said first and second dose by **automatically summing** values representing said first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient" as recited in claim 14 of the present invention. The Office Action agrees with this on pages 3 and 5. Additionally, Applicant respectfully submits that even if Wessol was combined with Burdette, Kestin, Helmick, Good and Widener, the combination would not make the present claimed invention unpatentable.

Burdette describes "carrying out minimally invasive treatments of the human body by virtual reality visualization of the treatment area ... [and] providing real time images of a human anatomy undergoing treatment along with rapid radiation seed therapy planning" (col. 1, lines 11-17). Nowhere in the Burdette is there any mention or suggestion of "scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record including said combined therapeutic dose value" as recited in claim 14 of the present invention. Burdette describes "computer software for real-time image acquisition, image contouring, dose calculation and display software, dose volume histograms, three-dimensional dose countours, post-implant seed localization" (col. 5, lines 17-21). "The system software enables a two-dimensional and three-dimensional image visualization for brachytherapy employing two-dimensional ultrasound imaging for use in radioactive seed implants of the prostate" (col. 5, lines 24-27).. Furthermore, Burdette describes a

> "transrectal ultrasound guided transperineal implant technique [that] has been developed ... That procedure [for the technique] is described in three steps: (1) the initial volumetric assessment of the prostate gland performed using ultrasound, (2) development of a radiation therapy 'pre-plan,' and (3) performing the actual intraoperative implant. The purpose of the initial volumetric assessment prior to the pre-plan or implantation is to obtain a quantitative understanding of the size of the prostate, which is then used to determine the total activity and distribution of radioactivity which is to be implanted into the prostate. To perform the assessment, an ultrasound probe is physically attached to a template ... Once the three-dimensional contour data has been obtained for the prostate volume, a radiation therapy plan which describes the positions of the radioactive seeds within the prostate is developed. This plan attempts to optimize the dose to the prostate, minimize the dose to surrounding healthy tissue, and minimize dose inhomogeneity. The positions of the radioactive seeds are constrained to fall within the catheter tracks, since the seeds are placed within the prostate transperineally via these catheters. The result of the pre-plan describes the positions and strengths of the radioactive seeds within the catheter which optimizes the dose to the prostate" (col. 2, lines 8-47).

Additionally, col. 4, lines 38-60 merely describes

> "[a] three-dimensional probe 12 [that] accumulates image data from a treatment region or organ of a patient, image data is processed using a three-dimensional imaging card ... A conventional personal computer 16 having a monitor can be used to operate on the image data from the imaging card ... Radioactive seeds 18 are provided for insertion ... which may be either needles or stiff catheters ... enabl[ing] a user to visualize a translucent image of the patient organ and real time interaction of any one of a variety of treatment devices, such as the implant needles 19 or a Foley catheter 20, and one of the seeds 18 within the organ. Computer software can be utilized in a conventional manner to visualize the three-dimensional imaging data in various formats" (col. 4, lines 39-61).

Furthermore, Fig. 1A is merely a block diagram of a three-dimensional probe. Thus, Burdette describe a brachytherapy system that monitors real-time placement of catheters. Additionally, Burdette describes an automated process "for loading … radioactive therapeutic treatment seeds based on a clinical plan enabling rapid treatment based on substantially real time pre-planning using rapid patient organ evaluations" (col. 3, lines 47-51). Real or near real time three-dimensional visualization of an organ undergoing treatment is provided. Hence, Burdette provides an improved brachytherapy system that automates the loading of needles/seeds "based upon a pre-plan (dose plan) determined in the operating room (OR)" (col. 10, lines 44-45). However, Burdette neither discloses nor suggests "combining data representing said first and second dose by automatically summing values representing said first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient" and "scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record including said combined therapeutic dose value" as recited in claim 14 of the present invention. Rather, Burdette is only concerned with the automatic loading of needles/seeds in order to view a real time three-dimensional visualization. Therefore, Burdette (with Wessol, Helmick, Kestin, Good and Widener) neither discloses nor suggests the features of the present claimed invention.

Helmick describes a case study conducted with nineteen test patients. The purpose of the Helmick study "was to evaluate the variability in dosimetry due to the change in prostate volume for permanent transperineal brachytherapy seed implant" (Abstract). Data was collected from the participants. "A spreadsheet was prepared to record the data collected. It was divided into 3 sections: TRUS preplan data, TRUS postplan data, and CT postplan data" (Materials and Methods, second paragraph). There were two groups of test patients and one patient was excluded from the study. Helmick has separate plans for external beam therapy and brachytherapy. Helmick describes that "Group A consisted of 3 cases that were treated with external-beam radiation therapy ... followed by a brachytherapy implant boost" (Materials and Methods, second paragraph). Therefore, in Helmick, any comparison or calculation is done manually and independently (*see* Fig. 1, "Original" and "Postimplant" values). This is wholly unlike the present claimed invention which **combines** "data representing said first and second dose by automatically summing values representing said first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient" as recited in claim 14. Additionally, Helmick nowhere discloses nor suggests "automatically storing said combined therapeutic dose value in an electronic record associated with said patient in a repository concurrently accessible by a plurality of healthcare workers using remote devices" as recited in claim 14 of the present invention.

Moreover, Helmick is directed towards dosimetric postplans, as recommended by the American Brachytherapy Society (ABS), for every patient after a prostate implant. The study conducted in Helmick concludes that different time intervals for performing CT scans will yield different total doses (*see* Discussion/Conclusion, second paragraph). Furthermore, Helmick concludes that the average coverage of 47% of the glands volume is due to "(a) CT scans taken too early while prostate edema is still influencing dosimetric coverage, and (b) inclusion of periprostatic tissues due to poor visualization of prostate margins … postimplant TRUS studies had an average prostate volume coverage of 74%. Based on this data ... the changes suggested by this work, coverage of 80% of the CT postimplant prostate volume is achievable with our current preplanning and implant technique" (Discussion/Conclusion, fourth and fifth paragraphs). Thus, Helmick is merely concerned with the change in prostate tumor volume at the end of a seed implant. Helmick takes measurements prior to and postplan and digitizes the images/tumor volumes (*see* Fig. 4). Additionally, Helmick concludes that the findings of the volumes treated tested and treated were too small, and that the process used should be changed to include higher percentage volumes. However, Helmick, similar to Burdette and Wessol (with Kestin, Good and Widener) neither discloses nor suggests "**scheduling and managing** a **sequence of tasks** involved in producing a treatment plan using said electronic record including said combined therapeutic dose value" as recited in claim 14 of the present invention.

Kestin describes a study of clinical trial patients with locally advanced prostate cancer that were prospectively treated with external beat RT in combination with high-dose-rate brachytherapy at William Beaumont Hospital and had post-RT biopsy material available for complete pathologic review conducted between 1991 and 1998. The goal of the study was to perform a detailed pathologic review of posttreatment biopsy specimens in an attempt to clarify their relationship with clinical outcomes and radiation doses. Although Kestin performs "a detailed pathologic analysis of all pretreatment and posttreatment biopsy specimens in patients prospectively treated with EBRT and HDR brachytherapy in an attempt to clarify their relationship with clinical outcome and radiation dose" (Introduction, fourth paragraph), Kestin does not disclose or suggest "combining data representing said first and second dose by **automatically summing** values representing said first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient" as recited in claim 14 of the present invention. Rather, Kestin is only concerned with pre-radiotherapy and posttreatment biopsy characteristics to determine if tissue samples taken were cancer free, as described in the "Results" section and Tables. Therefore, Kestin neither discloses nor suggests "combining data representing said first and second dose by automatically summing values representing said first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient" or "**automatically storing** said combined therapeutic dose value in an electronic record associated with said patient in a repository concurrently accessible by a plurality of healthcare workers using remote devices" as recited in claim 14 of the present invention.

Additionally, the study performed in Kestin is concerned with external beam radiotherapy (EBRT) and brachytherapy, however, Kestin does not disclose or suggest "a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient" as recited in claim 14 of the present invention. Also, as Kestin is concerned with pre-radiotherapy biopsy measurements and posttreatment biopsy characteristics and not with "scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record including said combined therapeutic dose value" as recited in claim 14 of the present invention.

Good provides a method for making radioactive spheres that may be used in radioactive therapy and treatment of a patient (*see* Abstract). This is fundamentally different from the present claimed system which seeks to monitor radioactive doses from different radioactive sources and recites "scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record including said combined therapeutic dose value" of radiation already received by the patient. Good merely describes mass producing an economical implantable radioactive device, in various shapes, sizes, coverings, and energies in a cost effective manner where the plant delivers high energy irradiation to a tumor site. Good also describes how the implant hopes to affect a cancer cell by releasing radiation. Good is wholly unlike and unrelated to the present claimed invention as Good merely describes producing a source of radiation that may be monitored using the claimed system.

Widener provides a surface mount radiation dosimeter that is able to evaluate the radiation dosage applied to a patient that is undergoing radiation therapy. These patches are applied to a patient and the dosage of radiation over each patch can be sensed and calculated. Thus, Widener is concerned with an external device used to monitor radiation delivered. Widener includes a disposable monitor which is attached to the patient and a reading device. A storage device stores the collected data and the data can be queried. The dose reader may utilize wireless technology. Widener may provide a mechanism to capture information regarding the dose of radiation, however, Widener fails to disclose or suggest producing a "combined therapeutic dose value" that is used for "scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record including" the combined therapeutic dose value stored therein, as recited in the present claimed invention. Additionally, Widener does not automatically store data in an electronic patient record, as in the present claimed invention. The present claimed invention, contrary to Widener, provides a fully integrated radiation treatment record. Widener, nowhere in the cited passages or figures discloses or suggests the features of the present claimed invention.

Additionally, Good and Widener (with Wessol, Burdette, Kestin and Helmick) are not at all concerned with "combining data representing said first and second dose by automatically summing values representing said first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient" and "scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record including said combined therapeutic dose value" as recited in claim 14 of the present invention. Rather, each of these systems, when taken alone or in any combination with one another, are concerned with entirely unrelated problems. Wessol merely creates an image to improve targeted radiation therapy for a patient. Burdette is concerned with virtual reality visualization of a patient's treatment area. Helmick and Kestin, which are completely unrelated to Wessol, Burdette, Good and Widener, merely describe the results of a studies performed for calculating the volumes of tumors before and after a treatment. Good describes how to produce a radiation source and Widener provides patches that may be used to measure radiation over a particular area on the body. This is fundamentally different from the claimed system because the claimed system facilitates treatment and planning of radiation therapy that complies with NRC safety regulations by surveying a total amount of radiation emitted by internal and external radiation sources and also emitted by the patient. Good, Widener, Wessol, Burdette, Kestin and Helmick provide no 35 USC 112 compliant enabling disclosure of these features.

Applicant respectfully submits that there is no motivation to combine any of the six systems and patient clinical studies. Wessol, Burdette, Kestin, Helmick, Good and Widener as they are all in fundamentally different areas of art. Specifically, Wessol is concerned with providing a geometric model of radiation applied to a patient to improve the view of how the radiation affects the patient. Burdette is concerned with virtual reality visualization of a patient's treatment area. Widener provides a patch that senses the amount of radiation being applied to a patient and Good provides a method for producing a source of the radiation used to treat a patient. Helmick and Kestin describe the results of a studies performed for calculating the volumes of tumors before and after a treatment. These references provide unrelated apparatus and clinical studies that each accomplishes entirely unrelated objectives. There would be no reason to combine an implantable device for emitting radioactive therapy (as in Good) with a system such as Wessol which computationally models the emitted radiation with respect to the body to aide in modifying the dosage of radiation used in treatment of the patient, with the studies performed by Helmick and Kestin. Moreover, a person of ordinary skill in the art would not find it obvious to combine all six references. Therefore, Applicant respectfully submits that there is no reason or motivation to combine these references.

Additionally, even if one were to combine these references, the result would not produce a system equivalent to the present claimed invention. The system resulting from the combination of Wessol, Burdette, Helmick, Kestin Good and Widener would not be structurally or functionally equivalent to the present claimed system. The combination neither discloses nor suggests a "combined therapeutic dose value" that is used in "scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record including" the combined therapeutic dose value stored therein. Rather, the combination would merely yield a system capable of measuring data and recording three-dimensional images of a cancerous area of a patient's body before and after external beam radiation and brachytherapy. The images would be provided in real-time. A patch would be included that senses the amount of radiation being applied to a patient. The radioactive implants used would be mass produced and versatile. However, the combined system does not store a "combined therapeutic dose value" which represents a "first and second dose by automatically summing values representing said first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient" in "an electronic record associated with said patient in a repository concurrently accessible by a plurality of healthcare workers using remote devices" as recited in claim 14 of the present invention. Although the combined system may describe a radiation therapy plan, the combined system neither discloses nor suggests "**scheduling and managing a sequence of tasks** involved in producing a **treatment plan** using said electronic record including said combined therapeutic dose value" as recited in claim 14 of the present invention. Therefore, the combined system does not make the present claimed invention unpatentable.

Therefore, as Wessol, Burdette, Helmick, Kestin, Good and Widener fail to show or suggest each feature in claim 14, Wessol, Burdette, Helmick, Kestin, Good and Widener, when taken alone or in any combination, do not make the present claimed invention unpatentable. Consequently, it is respectfully requested that the rejection of claim 14 under 35 U.S.C. 103(a) be withdrawn.

Claims 17 and 18 are not specifically rejected to in the Office Action under 35 USC 103(a). However, Applicant respectfully submits that these claims are dependent on claim 14 and are considered patentable over Wessol, Burdette, Helmick, Kestin, Good and Widener, when taken alone or in any combination.

In view of the above remarks, Applicant respectfully submits that Wessol, Burdette, Helmick, Kestin, Good and Widener, when taken alone or in any combination, do not make the present claimed invention unpatentable. Therefore, Applicant further respectfully submits that this rejection has been satisfied and should be withdrawn.

CLAIMS 15-18

Claims 15-18 are not rejected in the Office Action under either the first or second 35 USC 103(a) rejections. However, Applicant respectfully submits that claims 15 and 16 are considered patentable over Wessol, Burdette, Kestin, Helmick, Good and Widener, alone or in any combination, in view of their dependence on claim 12. Claim 15 is also considered patentable for similar reasons presented above with respect to claim 2. Claim 16 is also considered patentable for similar reasons presented above with respect to claim 3. Claims 17 and 18 are considered patentable over Wessol, Burdette, Kestin, Helmick, Good and Widener, alone or in any combination, in view of their dependence on claim 14. Claim 17 is also considered patentable for similar reasons presented above with respect to claim 4. Claim 18 is also considered patentable for similar reasons presented above with respect to claim 8. Therefore, Applicant respectfully submits that claims 15-18 are all allowable over Wessol, Burdette, Kestin, Helmick, Good and Widener, when taken alone or in any combination.

VIII CONCLUSION

Wessol, Burdette, Helmick, Kestin, Good and Widener, when taken alone or in any combination, neither disclose nor suggests "combining data representing said first and second dose by automatically summing values representing said first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient" and "a storage processor for automatically storing said combined therapeutic dose value in an electronic record associated with said patient in a repository concurrently accessible by a plurality of different healthcare workers using remote devices" as recited in claim 1 of the present invention. Additionally, Wessol, Burdette, Helmick, Kestin, Good and Widener, neither disclose nor suggest "a workflow processor for scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record including said combined therapeutic dose value" as recited in claim 1 of the present invention. Independent claims 12 and 14 contain similar features to claim 1, and are also allowed over Wessol, Burdette, Helmick, Kestin, Good and Widener, when taken alone or in any combination. As claims 2-11 are dependent on claim 1; claims 13, 15 and 16 are dependent on claim 12 and claims 17 and 18 are dependent on claim 14, these claims are also allowable over the cited references.

Accordingly it is respectfully submitted that the rejection of claims 1-18 should be reversed.

Respectfully submitted,

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APPENDIX I - APPEALED CLAIMS

1. (Previously Presented) A system for processing data concerning patient radiation treatment, comprising:

an input processor for receiving data identifying a first radiation dose, received by a particular anatomical part of a patient, from a radiation source external to a patient and a second radiation dose, received by said particular anatomical part of said patient from a radiation source internal to said patient and implanted within said patient;

a data processor for combining data representing said first and second dose by automatically summing values representing said first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient;

a storage processor for automatically storing said combined therapeutic dose value in an electronic record associated with said patient in a repository concurrently accessible by a plurality of different healthcare workers using remote devices and

a workflow processor for scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record including said combined therapeutic dose value.

2. (Previously Presented) A system according to claim 1, wherein

said input processor automatically acquires patient radiation survey record data from radiation survey equipment indicating radiation levels emitted by a patient, and

said storage processor stores said acquired patient radiation survey record data in said repository.

3. (Previously Presented) A system according to claim 1, wherein

said data processor automatically populates a patient radiation survey record form with data derived from radiation survey equipment indicating radiation levels emitted by a patient and

said radiation source internal to said patient comprises at least one of, (a) an implanted device, (b) an intra-vascular radiation treatment source, (d) a temporarily inserted radiation source, (e) a permanently inserted radiation source, (f) a diagnostic related radiation source and (g) a therapeutic radiation source.

4. (Previously Presented) A system according to claim 1, including

a rules processor for initiating generation of an alert message for communication to a healthcare worker, in response to said combined therapeutic dose value and automatically initiating generation of an alert message for communication to a healthcare worker, in response to determining inappropriate radiation settings of a radiation imaging or therapy device in response to said combined therapeutic dose value.

5. (Previously Presented) A system according to claim 1, wherein

said input processor receives data identifying a radiation value emitted by a radiation source implanted within a patient and

said storage processor stores said emitted radiation value and said combined therapeutic dose value in said record associated with said patient.

6. (Currently Amended) A system according to claim 5, wherein

said storage processor stores said emitted radiation value and said combined therapeutic dose value in at least one of, (a) the same portion of said record and (b) a related record section of said record, to consolidate radiation related data in a particular patient record section.

7. (Original) A system according to claim 1, wherein

said record associated with said patient includes at least one of, (a) an identification of said particular anatomical part of said patient, (b) said first radiation dose, (c) said second radiation dose and (d) data identifying a radiation value emitted by a radiation source implanted within a patient.

8. (Previously Presented) A system according to claim 1, including

a communication interface for initiating communication of an alert message to a user identifying said combined therapeutic dose value associated with said patient.

9. (Previously Presented) A system according to claim 1, including

a task manager for updating a record indicating a task to be performed by including an additional task in response to said combined therapeutic dose value.

10. (Original) A system according to claim 9, wherein

said additional task is to be performed by at least one healthcare worker and comprises a prompt to a healthcare worker to perform an action.

11. (Previously Presented) A system according to claim 1, including

an interface processor for using said combined therapeutic dose value in configuring a radiation therapy device for delivering a radiation treatment to a patient.

12. (Previously Presented) A system for processing data concerning patient radiation treatment, comprising:

an input processor for receiving data identifying a first radiation dose, received by a particular anatomical part of a patient, from a radiation source external to a patient and a second radiation dose, received by said particular anatomical part of said patient from a radiation source internal to said patient and implanted within said patient;

a data processor for combining data representing said first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient and including a rules processor for automatically initiating generation of an alert message for communication to a healthcare worker, in response to determining inappropriate radiation settings of a radiation imaging or therapy device in response to said combined therapeutic dose value;

a storage processor for automatically storing said combined therapeutic dose value in an electronic record associated with said patient in a repository concurrently accessible by a plurality of healthcare workers using remote devices; and a task manager for updating a record indicating a task to be performed by including an additional task in response to said combined therapeutic dose value.

13. (Previously Presented) A system according to claim 12 wherein

said input processor receives data identifying a radiation value emitted by a radiation source implanted within a patient and

said task manager updates a record to indicate a perimeter is to be designated identifying an area around said patient to be avoided by other personnel, in response to said combined therapeutic dose value.

14. (Previously Presented) A method for processing data concerning patient radiation treatment, comprising the activities of:

receiving data identifying a first radiation dose, received by a particular anatomical part of a patient, from a radiation source external to a patient and a second radiation dose, received by said particular anatomical part of said patient from a radiation source internal to said patient and implanted within said patient;

combining data representing said first and second dose by automatically summing values representing said first and second dose to provide a combined therapeutic dose value representing a total cumulative radiation dose received by said particular anatomical part of said patient;

automatically storing said combined therapeutic dose value in an electronic record associated with said patient in a repository concurrently accessible by a plurality of healthcare workers using remote devices and scheduling and managing a sequence of tasks involved in producing a treatment plan using said electronic record including said combined therapeutic dose value.

15. (Previously Presented) A system according to claim 12 wherein

said data processor automatically acquires and stores patient radiation survey record data from radiation survey equipment indicating radiation levels emitted by a patient.

16. (Previously Presented) A system according to claim 12, wherein

said data processor automatically populates a patient radiation survey record form with data derived from radiation survey equipment indicating radiation levels emitted by a patient.

17. (Previously Presented) A system according to claim 14, including the activity of

automatically initiating generation of an alert message for communication to a healthcare worker, in response to determining inappropriate radiation settings of a radiation imaging or therapy device in response to said combined therapeutic dose value.

18. (Previously Presented) A system according to claim 17, including the activity of

initiating generation of an alert message for communication to a healthcare worker, in response to said combined therapeutic dose value.

APPENDIX II - EVIDENCE

Applicant does not rely on any additional evidence other than the arguments submitted hereinabove.

APPENDIX III - RELATED PROCEEDINGS

Applicant respectfully submits that there are no proceedings related to this appeal in which any decisions were rendered.

APPENDIX IV - TABLE OF CASES

APPENDIX V - LIST OF REFERENCES

U.S. Patent/Pub No./Title	**Issued Date**	**102(e) Date**	**Inventors**
6,965,847	November 15, 2005		Wessol et al.
6,129,670	October 10, 2000		Burdette et al.
"Pathologic Evidence of Dose-Response and Dose-Volume Relationships for Prostate Cancer Treated with Combined External Beam Radiotherapy and High-Dose-Rate Brachytherarpy"	May 2, 2002		Kestin et al.
"Evaluation of Post-Plan Dosimetery Using TRUS and CT After Transperineal Prostate Seed Implant"	April 15, 2001		Helmick et al.
6,099,457	August 8, 2000		Good
2004/0236207	November 25, 2004		Widener et al.

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